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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,534	01/19/2001	Kari Alitalo	28967/34891A	1420
4743	7590	01/25/2005	EXAMINER	
MARSHALL, GERSTEIN & BORUN LLP 6300 SEARS TOWER 233 S. WACKER DRIVE CHICAGO, IL 60606			MURPHY, JOSEPH F	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/765,534

Applicant(s)

ALITALO ET AL.

Examiner

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-33 is/are pending in the application.
4a) Of the above claim(s) 25-30 is/are withdrawn from consideration.
5) ☒ Claim(s) 20-24 and 31-33 is/are allowed.
6) ☒ Claim(s) 19 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11122004.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

Claims 19-33 are pending. Claims 25-30 stand withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 19-24, 31-33 are under consideration.

Response to Amendment

The objections to the claims have been obviated by Applicant's amendment and are thus withdrawn.

The Declaration under 37 CFR 1.132 filed 11/12/2004 is sufficient to overcome the rejection of claims 20-24, 31-33 based upon 35 USC §§112 first paragraph; 102(b).

The Declaration under 37 CFR 1.132 filed 11/12/2004 is insufficient to overcome the rejection of claim 19 based upon 35 USC 112 first paragraph as set forth in the last Office for the reasons set forth below.

Remaining issues are also set forth below.

Double Patenting

Claims 19-24, 31-33 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 38-44 of U.S. Patent No. 5,776,755, for reason of record set forth in the Office action of 6/11/2004. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

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Applicant has indicated that a terminal disclaimer will be filed, however, this rejection is maintained until such time as the terminal disclaimer is received.

Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 19 stands rejected under 35 U.S.C. 112, first paragraph, because the specification, which is enabling for a full-length flt4 of SEQ ID NO: 2 or 4, or a flt4 polypeptide comprising amino acids 1-775 of SEQ ID NO: 2 or 4, or a flt4 polypeptide comprising amino acids 21-775 of SEQ ID NO: 4, does not reasonably provide enablement for a flt4 fragment encoded by 200 nucleotides of SEQ ID NO: 1 or 3 for reason of record set forth in the Office action of 6/11/2004. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to a flt4 fragment encoded by 200 nucleotides of SEQ ID NO: 1 or 3. No functional limitation is set forth in the claim. Claim 19 is overly broad since insufficient guidance is provided as to which of the myriad of variant polypeptides will retain the characteristics of flt4. The claims are directed to variant polypeptides. However, Applicants do not disclose any actual or prophetic examples on expected performance parameters of any of the possible variants of flt4. It was established in the previous Office Action that the effect of variation on protein function is unpredictable. Since the claims encompass variant polypeptides and given the art recognized unpredictability of the effect of variations on protein function, it

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would require undue experimentation to make and use the claimed invention. Applicant argues that the claims encompass polypeptides that would be useful for antibody production, and provides a Declaration by Dr. Alitalo that the specification discloses the use of flt4 polypeptides for the production of antibodies specific for flt4. However, while this limitation is present in claims 20-24, 31-33, thereby overcoming the rejection, this limitation is not present in claim 19 as written, and therefore the rejection is maintained. Applicant is required to enable one of skill in the art to make and use the claimed invention, while the claims encompass polypeptides that the specification only teaches one skilled in the art to test for functional variants. It would require undue experimentation for one of skill in the art to use the claimed polypeptide variants, since the skilled artisan would have to first make polypeptide variants of flt4, then test for function. Because the amino acid sequence of a polypeptide determines its structural and functional properties, and predictability of which amino acids can be varied is extremely complex, accurate predictions of a polypeptide's structure and function from mere sequence data are limited. Thus, since Applicant has only taught how to test for polypeptide variants of flt4, and has not taught how to make or use polypeptide variants of flt4, it would require undue experimentation of one of skill in the art to make and use the claimed polypeptides.

Claim 19 stands rejected, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record set forth in the Office action of

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6/11/2004. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The claims are drawn to a flt4 fragment encoded by 200 nucleotides of SEQ ID NO: 1 or 3. No functional limitation is set forth in the claim. Applicant argues that the claims encompass polypeptides that would be useful for antibody production, and provides a Declaration by Dr. Alitalo that the specification discloses the use of flt4 polypeptides for the production of antibodies specific for flt4. However, while this limitation is present in claims 20-24, 31-33, thereby overcoming the rejection, this limitation is not present in claim 19 as written, and therefore the rejection is maintained. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. In the instant case, the claim fails to disclose a correlation between structure and function, since no function is set forth. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

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Conclusion

Claim 19 is rejected.

Claims 20-24, 31-33 are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

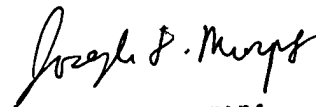
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961.

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The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
January 11, 2005


JOSEPH MURPHY
PATENT EXAMINER